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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Staci Zegler Plaintiff, v. Smith & Nephew, Inc. and Smith & Nephew GmbH, Defendants	Case No.: _____ **Plaintiff's Complaint And Jury Demand**

PLAINTIFF'S COMPLAINT AND JURY DEMAND

Plaintiff, by and through counsel, Davis, Saperstein & Salomon P.C., upon information and belief, at all times hereinafter mentioned, alleges as follows:

1. This Complaint is brought on behalf of Plaintiff Staci Zegler who suffered damages as a direct and proximate result of the Defendant's negligent and wrongful misconduct in connection with the development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, and sale of the Smith & Nephew R3 Ceramic Biolox Forte acetabular hip liner ("R3 ceramic liner").

PARTIES

2. Plaintiff Staci Zegler is a resident and citizen of Jersey City, Hudson County, New Jersey.

3. Defendant SMITH & NEPHEW, INC. is a company engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, advertising, marketing, distributing, labeling, and selling medical devices, including the R3 ceramic liner.

4. Defendant SMITH & NEPHEW, INC. is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware with offices located in 1450 Brooks Road, Memphis, Tennessee 38116. Defendant SMITH & NEPHEW, INC. transacts business around the world, in the United States, and in the State of New Jersey.

5. Defendant SMITH & NEPHEW, INC. marketed the R3 Ceramic liner in the U.S. after it was approved by the Food and Drug Administration ("FDA") as "substantially equivalent to legally marketed predicate devices" on February 18, 2008.

6. Defendant SMITH & NEPHEW, INC. is a U.S. subsidiary of Smith & Nephew PLC.

7. Defendant SMITH & NEPHEW, INC. is hereinafter referred to as "Smith & Nephew," or "Defendant."

JURISDICTION AND VENUE

8. This court has subject matter jurisdiction under 28 U.S.C. § 1332, based on diversity of citizenship between the parties, and the amount in controversy exceeding $75,000 (seventy-five thousand dollars) exclusive of interest and costs.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(a) and (c), as the Defendant conducts business, sales activity, and maintains a registered agent in this district. Thus, the Defendant is subject to personal jurisdiction in this district.

FACTUAL ALLEGATIONS

A. Hip Replacement Surgery

10. Hip joint deterioration or arthritis can lead to pain, stiffness or difficulty walking. When these symptoms do not respond to conservative treatment, patients may undergo total hip replacement.

11. During total hip replacement surgery, the damaged portions of the hip joint are removed. The ball (femoral head) is removed and replaced with a prosthetic ball made of metal or ceramic, and the socket (acetabulum) is removed and replaced with a prosthetic acetabular shell. The shell consists of one or two components made of either metal, ceramic, or plastic. An acetabular liner fits into an acetabular shell with a coating which is then attached to a bone for ambulation. The acetabular liner is made of either metal, ceramic, or plastic. A stem is also implanted in the femur to support the femoral head. The femoral head attaches to the taper of the stem.

B. Plaintiff's Implant Surgery

12. Plaintiff, Staci Zegler, was born on March 21, 1965.

13. On or about March 11, 2010, Plaintiff underwent right total hip arthroplasty surgery at Hospital for Special Surgery in New York, New York, performed by Dr. David Mayman. On or about August 1, 2013, Plaintiff underwent left total hip arthroplasty surgery at Hospital for Special Surgery in New York, New York, performed by Dr. David Mayman.

14. In connection with performing these surgeries, Dr. Mayman implanted the following products in Plaintiff on March 11, 2010, which were manufactured and marketed by the Defendant Smith & Nephew: (a) R3 O Hole Shell, Lot # 10BM0714; (b) R3 Ceramic Biolox Forte acetabular hip liner, Lot# 09FT32504 (the "R3 ceramic liner"); (c) Anthology Porous High Offset PL HA Stem, Lot # 09BM1271; (d) Ceramic Biolox Femoral Head, 36mm, +0

12/14 Lot# 09FM1084, (e) Cover, Threaded Hole, Lot# 09MM0934. On August 1, 2013, Dr. Mayman implanted the following products in Plaintiff, which were manufactured and marketed by the Defendant Smith & Nephew: (a) R3 O Hole Shell, Lot# 13FM08797; (b) R3 XLPE Acetabular Liner, Lot# 13EM20275; (c) Porous Plus High Offset Stem, Lot# 71309111; (d) Femoral Head, 36mm, +0 12/14 Lot# 13DM20159.

15. On March 21, 2011, alignment of the prosthetic components was satisfactory. On December 19, 2012, it was reported that there was no evidence of interval hardware complication , after implantation of the R3 ceramic liner, Dr. Mayman noted that the left total hip replacement was in good position.

C. The R3 Ceramic Liner and the FDA Investigation

16. On or about March 2010 through June 30, 2009, when Plaintiff was implanted with the R3 ceramic liner and after, Smith & Nephew issued and advertised to the public an R3 Actebular System Design Rationale (the "R3 Design Rationale"). The R3 Design Rationale touted the R3 ceramic liner as: "New technology; Improved manufacturing processes and standards; New designs. This translates into improvements in the following: Mechanical and physical properties; Wear characteristics; Optimized biocompatibility; Reliability expected by today's more active patients".

17. The R3 Design Rationale also touted: "Due to the reduced grain size, ceramic components are harder than before. That has led to wear rates as low as 0.00lmm/year." Further, the R3 Design Rationale stated: "Impingement in ceramic bearing systems increases wear and decreases implant longevity. The improved design of R3 ceramic acetabular components: Reduces the effects of impingement; Enhances wear and durability by utilizing liners that sit flush with the shell face".

18. The R3 Design Rational also stated: "The unique feature about R3 ceramic liners is that they come with a titanium support ring around the periphery of the liner. The support ring and ceramic liner are precisely assembled utilizing a cold pressing process, which assures that the material properties of the ceramic and titanium are not altered. Lab tests have shown that the

burst strength of these liners is significantly higher than that of traditional ceramic liners with no band. Based on these test results, it can be hypothesized that these liners with titanium band would reduce the incidence of fracture of the ceramic liners."

19. Unbeknownst to Plaintiff or Plaintiff's treating physicians, in July 2010 the FDA investigated the plant which manufactured the titanium ring and assembled the R3 ceramic liner and is owned by Smith & Nephew in Tuttlingen, Germany. The FDA inspection found that Smith & Nephew's R3 ceramic liners were "adulterated within the meaning of Section 501 (h) of the [Food, Drug, and Cosmetic] Act ("FDCA") (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, are not in conformity with the Current Good Manufacturing Practice ("CGMP") requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820."

20. Among other things, the FDA determined in July 2010, coincident with Plaintiff's implant surgery with the defective R3 ceramic liner, that "[t]here was no process validation study to support the minimum and maximum settings being used on the [redacted] [equipment] for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner." This is the very process Smith & Nephew touted resulted in R3 ceramic liners being stronger than traditional liners in its advertisements and representations to the medical community, including Plaintiff's physicians, and patients, including Plaintiff. Yet, Smith & Nephew failed to comply with its own processes and manufacture the R3 ceramic liners in accordance with FDA manufacturing specifications as confirmed by the FDA's December 2010 Warning Letter and Defendant's ultimate recall of batches of the R3 ceramic liner, including the R3 ceramic liner that was implanted in Plaintiff, for failing to meet manufacturing specifications.

21. Smith & Nephew has since acknowledged that, due to inadequate quality controls, the titanium rings were pressed into R3 ceramic liners with a higher force than specified for a number of batches, and Smith & Nephew ultimately recalled batches of the R3 ceramic liners. As a result, these R3 ceramic liners had the potential to fracture earlier and at a higher rate than

expected. In the event of a R3 ceramic liner fracture, an immediate surgical revision is necessary. Revision surgery may also be indicated if a R3 ceramic liner fracture is possible.

22. Although the FDA immediately raised concerns with Smith & Nephew in July 2010, the company took no steps to recall or quarantine the products in question. Smith & Nephew also failed to warn the medical community and patients, including Plaintiff, of possible concerns. As a result, neither Plaintiff nor Plaintiff's treating physicians had any idea that a defective R3 ceramic liner that failed to meet manufacturing specifications was implanted into Plaintiff.

23. Rather than recalling the device or warning the medical community and patients, Smith & Nephew assured the FDA that, based on its own internal analysis, the R3 ceramic liner was suitable for use. Smith & Nephew also said it returned the controls on the press used to manufacture the device to its proper settings and would ensure that such settings remained proper in the future.

24. The FDA, however, issued a Warning Letter to Smith & Nephew on December 21, 2010, which categorically rejected Smith & Nephew's response. The FDA response highlighted that Smith & Nephew "did not provide a testing protocol or statistical rationale" to support its analysis, and that it "did not describe how procedures to verify or validate corrective and preventive action would be established or revised." Specifically, the FDA determined that Defendant failed to conform the R3 ceramic liner to its PMA specifications by violating the following federal regulations:

(a) Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21CFR820.75(a). For example: (i) There was no process validation study to support the minimum and maximum settings being used on the [redacted] for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner. (ii) Bioburden and endotoxin testing were not performed for the Tibia Base Plates as required by the performance qualification studies for the [redacted] and [redacted] Washers used during R3 Ceramic Acetabular Liner production;

(b) Failure to establish and maintain adequate procedures to verify or validate

corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example: According to the firm's management, based upon the investigation of the cause of irradiation batches receiving doses below the specified minimum dose requirement (due to incorrect packaging and product density), in May of 2009, the firm implemented new packaging procedures and retrained employees. Irradiation batches receiving doses below the specified minimum dose requirement have recurred after implementation of the cited corrective action (e.g., Irradiation Batch Nos. [redacted] and [redacted]. The firm's management stated that the recurring nonconformities may be attributed to employees not following directions;

(c) Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example: No evaluation was conducted to determine the need for an investigation of Irradiation Batch Nos. [redacted] and [redacted] that failed to meet specified minimum dose requirements. No investigation of these nonconformances was conducted;

(d) Failure to document the justification for use of nonconforming product and the signatures of the individual(s) authorizing the use, as required by 820.90(b). For example: Irradiation Batch Nos. (consisting of a variety of products including R3 Ceramic Acetabular Liners) [redacted] and [redacted] that failed to meet specified minimum dose requirements were released and distributed. No documented justification (including the signature of the individual(s) authorizing the use) for the use of this nonconforming product was provided during the inspection; and

(e) Failure to establish procedures for changes to a specification, method, process, or procedure, as required by 21 CFR 820.70(b). For example: Changes were made to the minimum and maximum settings in the [redacted] press for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner without undergoing a formal review and approval process per Specifications [redacted] and [redacted]. *(See* December 21, 2010 FDA Letter to Smith & Nephew, Exhibit A, attached.)

25. On or about April 22, 2011, Smith & Nephew issued a recall for numerous batches of the R3 ceramic liner, including the R3 ceramic liner that was implanted in Plaintiff only a year earlier. The Class 2 recall advised doctors and patients that due to a manufacturing defect characterized as a "TRAINING: Employee Error", the ceramic acetabular component had lower than expected strength for the liners.

D. Plaintiff's Injuries and Revision Surgeries

26. On January 17, 2013, Dr. Mayman performed revision surgery on Plaintiff's right hip at Hospital for Special Surgery.

27. During the January 17, 2013 revision surgery, Dr. Mayman discovered that the ceramic liner had fractured into two separate pieces. The pathologist also reported a thin layer of synovial lining cells covering most surfaces which included particles of ceramic debris.

28. Plaintiff's R3 ceramic liner, despite Smith & Nephew's representations about its manufacturing process resulting in a burst strength that was significantly higher than that of traditional ceramic liners, fractured into pieces within three years from when it was implanted. Defendant's failure to manufacture the R3 ceramic liner in accordance with FDA specifications resulted in Plaintiff's liner prematurely fracturing and Plaintiff's subsequent injuries.

29. Defendant, its agents, servants and/or employees designed, developed, manufactured, tested, packaged, promoted, advertised, marketed, distributed, labeled, and sold the R3 liner without making proper and sufficient tests to determine the dangers thereof, and without sufficiently warning the public and the medical community of the risks inherent in its use, as well as the dangers, and side-effects inherent in the device.

30. Defendant failed to conduct tests to confirm that the R3 ceramic liner conformed with its Pre-Market Approval ("PMA") FDA specifications.

31. Defendant acted intentionally, purposely, recklessly, and/or negligently when advertising, marketing and recommending use of the R3 ceramic liner as a safe and effective device without sufficient warning of its dangerous propensities; represented that the R3 ceramic liner was safe for implantation and for its intended purpose, when in fact it was unsafe; and otherwise failed to appropriately warn users, including Plaintiff and the medical community of the dangers and side-effects inherent in the R3 ceramic liner. Defendant also acted intentionally, purposely, recklessly and/or negligently by failing to conduct sufficient, adequate and

appropriate testing to determine whether or not the R3 ceramic liner was safe for its intended use.

32. Defendant knew or should have known that the R3 ceramic liner was unsafe and unfit for use based upon the state of knowledge as it existed at the time, and upon generally accepted medical and research standards and principles, by reason of its dangerous propensities.

33. Defendant, its agents, servants, and/or employees, improperly obtained the approval of the FDA to market the R3 ceramic liner by misrepresenting its risks; and acted otherwise intentionally, purposely, recklessly, and negligently.

34. Plaintiff and her doctors used the R3 ceramic liner in the manner for which it was designed, developed, manufactured, tested, packaged, promoted, advertised, marketed, distributed, labeled, and sold by Defendant.

35. By reason of the foregoing acts and omissions by Defendant, whereby Defendant failed to conform the R3 ceramic liner to its PMA specifications in violation of CGMP requirements of the Quality System, 21 C.F.R., Part 820, requirements described below which specifically govern the R3 ceramic liner, Plaintiff's liner fractured prematurely resulting in revision surgery. Plaintiff has sustained severe, serious, and permanent personal injuries, requiring hospitalization, and medical care; Plaintiff will require future hospitalizations, surgeries, and lifelong care; will be precluded from having a normal life, physically, vocationally, emotionally, and psychologically; and has been otherwise damaged.

36. The applicable statute of limitations is tolled based on Defendant's fraudulent concealment of the dangers and adverse side effects of the R3 ceramic liner from Plaintiff as more fully stated herein. Additionally, for the reasons stated herein, Defendant is equitably estopped from raising the statute of limitations defense.

CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY - MANUFACTURING DEFECT

37. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

38. Defendant designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the R3 ceramic liner, in a condition which rendered it unreasonably dangerous due to its propensity to fracture. The R3 ceramic liner was unreasonably dangerous in construction and/or composition.

39. The R3 ceramic liner manufactured and/or supplied by Defendant was defective in manufacture, construction and/or composition in that, when it left the hands of Defendant, it deviated in a material way from Defendant's manufacturing performance standards and/or it differed from otherwise identical products manufactured from the same design.

40. The FDA confirmed on several occasions that Defendant's R3 ceramic liner failed to conform to manufacturing specifications. The FDA concluded that Defendant's R3 ceramic liner was adulterated within the meaning of Section 50l(h) of the [Food, Drug, and Cosmetic] Act ("FDCA") (21 U.S.C. § 351 (h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, were not in conformity with the Current Good Manufacturing Practice ("CGMP") requirements of the Quality System (QS) regulation found at Title 21 , Code of Federal Regulations (C.F.R.), Part 820."

41. Among other things, the FDA dete1mined in July 2010 that "[t]here was no process validation study to support the minimum and maximum settings being used on the (b)(4) [equipment] for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner."

42. The FDA further determined that Defendant failed "to establish and maintain adequate procedures to verify or validate corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CPR 820.100(a)(4)."

43. Specifically, the FDA determined that Defendant failed to conform the R3 ceramic liner to its PMA specifications by violating the following federal regulations:

(f) Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CPR 820.75(a). For example: (i) There was no process validation study to support the minimum and maximum settings being used on the [redacted] for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner. (ii) Bioburden and endotoxin testing were not performed for the Tibia Base Plates as required by the performance qualification studies for the [redacted] and [redacted] Washers used during R3 Ceramic Acetabular Liner production;

(g) Failure to establish and maintain adequate procedures to verify or validate corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CPR 820.100(a)(4). For example: According to the firm's management, based upon the investigation of the cause of irradiation batches receiving doses below the specified minimum dose requirement (due to incorrect packaging and product density), in May of 2009, the firm implemented new packaging procedures and retrained employees. Irradiation batches receiving doses below the specified minimum dose requirement have recurred after implementation of the cited corrective action (e.g., Irradiation Batch Nos. [redacted] and [redacted]. The firm's management stated that the recurring nonconfo1mities may be attributed to employees not following directions;

(h) Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CPR 820.90(a). For example: No evaluation was conducted to determine the need for an investigation of Irradiation Batch Nos. [redacted] and [redacted] that failed to meet specified minimum dose requirements. No investigation of these nonconformances was conducted;

(i) Failure to document the justification for use of nonconforming product and the signatures of the individual(s) authorizing the use, as required by 820.90(b). For example: Irradiation Batch Nos. (consisting of a variety of products including R3 Ceramic Acetabular Liners) [redacted] and [redacted] that failed to meet specified minimum dose requirements were released and

> distributed. No documented justification (including the signature of the individual(s) authorizing the use) for the use of this nonconforming product was provided during the inspection; and
>
> (j) Failure to establish procedures for changes to a specification, method, process, or procedure, as required by 21 CPR 820.70(b). For example: Changes were made to the minimum and maximum settings in the [redacted] press for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner without undergoing a formal review and approval process per Specifications [redacted] and [redacted]. *(See* December 21, 2010 FDA Letter to Smith & Nephew, Exhibit A, attached.)

44. Defendant has since acknowledged that, due to inadequate quality controls, the titanium rings were pressed into the R3 ceramic liner with a higher force than specified for a number of batches. As a result, these R3 ceramic liners, including the R3 ceramic liner implanted in Plaintiff, had the potential to fracture earlier and at a higher rate than expected.

45. Defendant knew or should have known that the R3 ceramic liner could fail early in patients therefore giving rise to pain and suffering, debilitation, and the need for revision surgery to replace the R3 ceramic liner with the attendant risks of complications and death from such further surgery. Despite the aforementioned, Defendant continued to market the R3 ceramic liner as a safe and effective product. Within three years of being implanted in Plaintiff, the R3 ceramic liner fractured into pieces. Consistent with the FDA' s July 2010 investigation and findings Plaintiff's R3 ceramic liner was adulterated and failed to conform to FDA specifications which ultimately resulted in Defendant later recalling Plaintiff's liner and similarly adulterated liners.

46. The R3 ceramic liner implanted in Plaintiff was further designed in violation of the FDCA and regulations promulgated pursuant to it regarding Defendant's duties after the R3 ceramic liner received approval from the FDA.

47. The Defendant had the duty to manufacture the R3 ceramic liner in compliance with the FDCA, and all regulations promulgated pursuant to it which are specific to the R3 ceramic liner.

48. Notwithstanding this duty, the Defendant violated the FDCA in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the R3 ceramic liner in violation of 21 C.F.R. 820.JO(f);

b. Failed to establish and maintain appropriate reliability assurance testing to validate the R3 ceramic liner design before and after its release into the marketplace, in violation of21 C.F.R. 820.JO(g);

c. Failed to identify the R3 ceramic liner's component discrepancy, in violation of 21 C.F.R. 820.80(c);

d. Failed to capture the R3 ceramic liner's component discrepancy and defect during its Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

e. Failed to establish and maintain procedures for implementing corrective and preventative action in response to complaints regarding the R3 ceramic liner and/or other quality problems associated with the R3 liner in violation of 21 C.F.R. 820.100;

f. Failed to appropriately respond to adverse incident reports that indicated the R3 ceramic liner was malfunctioning, or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. 820.198;

g. Failed to conduct complete device investigations on returned R3 ceramic liners in violation of21 C.F.R. 820.198; and,

h. Continued to inject R3 ceramic liners into the stream of interstate commerce when it knew, or should have known, that the R3 ceramic liner was malfunctioning [as defined by 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent.

49. Defendant's failure to manufacture the R3 ceramic liner to its PMA specifications, in that there was no process validation study to support the minimum and maximum settings being used on the R3 ceramic liner's equipment for pressing different sized Titanium rings onto various ceramic inserts for the R3 ceramic liners, violated the above federal statutes and regulations, causing Plaintiff’s ceramic liner to fracture prematurely and for Plaintiff to suffer severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering, for which she is entitled to relief.

50. Plaintiff alleges that Defendant violated federal safety statutes and regulations described above that run parallel to state common law claims.

51. Plaintiff's R3 liner fractured prematurely, within three years from implant, due to Defendant's failure to comply with FDA PMA specifications resulting in the FDA's warning letter and Defendant's ultimate recall.

52. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture of the R3 ceramic liner, Plaintiff's R3 ceramic liner prematurely fractured, requiring revision surgery. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

53. As a direct and proximate result of the use of the R3 ceramic liner as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant and failure to comply with its own manufacturing specifications, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
STRICT LIABILITY - FAILURE TO WARN

54. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

55. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the R3 ceramic liner, in the course of same, directly advertised or marketed the R3 ceramic liner to the FDA, health care professionals, and consumers, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of the R3 ceramic liner.

56. Defendant failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's physicians, of the true risks of the R3 ceramic liner, including that the R3 ceramic liner was adulterated and could fracture, causing severe pain and injury, and requiring further treatment, including revision surgery.

57. Defendant failed to timely and reasonably warn of material facts regarding the safety and efficacy of the R3 ceramic liner, including that fact that it was adulterated, failed to conform to its PMA specifications, and could fracture. Had it done so, in timely fashion, proper warnings would have been heeded and no health care professional, including Plaintiff's physicians, and patients, including Plaintiff, would have used the defective R3 ceramic liner for her surgery in March 2010.

58. The R3 ceramic liner, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendant, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendant knew or should have known that there was reasonable evidence that the R3 ceramic liner failed to conform to manufacturing specifications and could fracture prematurely causing serious injury and pain. Defendant failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the R3 ceramic liner.

59. The R3 ceramic liner, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendant, was defective due to inadequate post-marketing

warnings and/or instruction regarding the increased risk of fracture of the R3 ceramic liner resulting in revision surgery while knowing that a safer alternative design existed, including but not limited to Smith & Nephew's R3 metal liners and R3 plastic liners.

60. Defendant failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the R3 ceramic liner, even though it provides no clinical benefit over other similar products, and had a higher fracture rate than other similar products.

61. The FDA confirmed on several occasions that Defendant's R3 ceramic liner failed to conform to manufacturing specifications. The FDA concluded that Defendant's R3 ceramic liner was adulterated within the meaning of Section 501(h) of the [Food, Drug, and Cosmetic] Act ("FDCA") (21 U.S.C. § 351 (h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, were not in conformity with the Current Good Manufacturing Practice ("CGMP") requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820."

62. Among other things, the FDA determined in July 2010 that "[t]here was no process validation study to support the minimum and maximum settings being used on the (b) 4) [equipment] for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner."

63. The FDA further determined that Defendant failed "to establish and maintain adequate procedures to verify or validate corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CPR 820.100(a)(4)."

64. Specifically, the FDA determined that Defendant failed to conform the R3 ceramic liner to its PMA specifications by violating the federal regulations detailed above and cited in the FDA's December 21 , 2010 Warning Letter to Smith & Nephew.

65. Defendant has since acknowledged that, due to inadequate quality controls, the titanium rings were pressed into the R3 ceramic liner with a higher force than specified for a number of batches and ultimately recalled batches of the R3 ceramic liner, including the R3 ceramic liner implanted in Plaintiff. As a result, these R3 ceramic liners had the potential to fracture earlier and at a higher rate than expected.

66. Defendant knew or should have known that the R3 ceramic liner could fail early in patients therefore giving rise to pain and suffering, debilitation, and the need for revision surgery to replace the R3 ceramic liner with the attendant risks of complications and death from such further surgery. Despite the aforementioned, Defendant continued to market the R3 ceramic liner as a safe and effective product. As a result, within three years of being implanted in Plaintiff, the R3 ceramic liner fractured into pieces. Consistent with the FDA's July 2010 investigation and findings, Plaintiff's R3 ceramic liner was adulterated and failed to conform to FDA specifications which ultimately resulted in Defendant later recalling Plaintiff's liner and similarly adulterated liners.

67. As described above, Defendant failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

68. As a direct and proximate result of the conduct of Defendant as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

69. The R3 ceramic liner implanted in Plaintiff was further sold in violation of the FDCA and regulations promulgated pursuant to it regarding Defendant's duties after the R3 ceramic liner received approval from the FDA.

70. Defendant's failure to manufacture the R3 ceramic liner to its PMA specifications, in that there was no process validation study to support the minimum and maximum settings being used on the R3 ceramic liner's equipment for pressing different sized Titanium rings onto various ceramic inserts for the R3 ceramic liners, violated the above federal statutes and regulations,

causing Plaintiff to suffer severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering, for which she is entitled to relief.

71. Plaintiff alleges that Defendant violated federal safety statutes and regulations described above that run parallel to state common law claims.

72. Plaintiff's R3 liner fractured prematurely, within three years from implant, due to Defendant's failure to comply with FDA PMA specifications resulting in the FDA's initial investigation in July 2010, the FDA's December 2010 Warning Letter and Defendant's ultimate recall.

73. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture and inadequate warnings of the R3 ceramic liner, Plaintiff's liner prematurely fractured, requiring revision surgery. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

74. Defendant's conduct, as described above, was reckless. Defendant risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendant made conscious decisions not to redesign, re-label, remanufacture, warn or inform the unsuspecting consuming public. Defendant's reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys ' fees and all such other relief as the Court deems proper.

COUNT III
NEGLIGENCE

75. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

76. At all relevant times, Defendant had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the R3 ceramic liner, including a duty to ensure that the R3 ceramic liner did not pose a significantly increased risk of bodily injury.

77. Defendant had a duty to exercise reasonable care in the advertising and sale of the R3 ceramic liner, including a duty to warn Plaintiff and other consumers of the dangers associated with the R3 ceramic liner that were known or should have been known to Defendant at the time of the sale of the R3 ceramic liner to the Plaintiff.

78. Defendant failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the R3 ceramic liner because Defendant knew or should have known that the R3 ceramic liner failed to conform to manufacturing specifications and therefore had a propensity to fracture and cause serious injury, including diminished mobility, and the need for revision surgery.

79. Defendant failed to exercise ordinary care in the labeling of the R3 ceramic liner and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including, that Defendant failed to conform to manufacturing specifications leading to premature fracture and the need for revision surgery, and the increased risk of failure when compared to similar products.

80. Defendant knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

81. The FDA confirmed on several occasions that Defendant's R3 ceramic liner failed to conform to FDA specifications. The FDA concluded that Defendant's R3 ceramic liner was adulterated within the meaning of Section 501 (h) of the [Food, Drug, and Cosmetic] Act ("FDCA") (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, were not in conformity with the Current Good Manufacturing Practice ("CGMP") requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820."

82. Among other things, the FDA determined in July 2010, at least three months before Plaintiff's surgery with the defective R3 ceramic liner, that "[t]here was no process validation study to support the minimum and maximum settings being used on the (b)(4) [equipment] for pressing different sized Titanium rings onto various ceramic inserts for the R3 Ceramic Acetabular Liner." Those failures also existed prior to Plaintiff's surgery in June 2009 on information and belief.

83. The FDA further determined that Defendant failed "to establish and maintain adequate procedures to verify or validate corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4)." This failure also existed before Plaintiff's June 2009 surgery on information and belief.

84. Specifically, the FDA determined that Defendant failed to conform the R3 ceramic liner to its PMA specifications by violating the following federal regulations as detailed above and cited in the FDA's December 21 , 2010 Warning Letter to Smith & Nephew.

85. Defendant has since acknowledged that, due to inadequate quality controls, the titanium rings were pressed into the R3 ceramic liner with a higher force than specified for a number of batches and ultimately recalled batches of the R3 liner, including the R3 liner implanted in Plaintiff. As a result, these R3 ceramic liners had the potential to fracture earlier and at a higher rate than expected.

86. As a direct and proximate result of Defendant's acts and omissions, including its failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the R3 ceramic liner, Plaintiff was implanted with the R3 ceramic liner and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, immobility, and pain and suffering for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

87. Defendant breached its duty of reasonable care to Plaintiff by failing to exercise due care to manufacture the R3 ceramic liner in compliance with the FDCA, and all regulations promulgated pursuant to it.

88. Defendant's failure to manufacture the R3 ceramic liner to its PMA specifications, in that there was no process validation study to support the minimum and maximum settings being used on the R3 ceramic liner's equipment for pressing different sized Titanium rings onto various ceramic inserts for the R3 ceramic liners, violated the above federal statutes and regulations, causing Plaintiff to suffer severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering, for which she is entitled to relief.

89. Plaintiff alleges that Defendant violated federal safety statutes and regulations described above that run parallel to state common law claims.

90. Plaintiff's R3 liner fractured prematurely, within three years from implant, due to Defendant's failure to comply with FDA PMA specifications resulting in the FDA's initial investigation in July 2010, the FDA's December 2010 Warning Letter and Defendant's ultimate recall.

91. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture and inadequate warnings of the R3 ceramic liner, Plaintiff's liner prematurely fractured, requiring revision surgery. Plaintiff has sustained and will

continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

92. Defendant's conduct, as described above, was reckless. Defendant risked the lives of consumers and users of their product, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendant made conscious decisions not to redesign, re-manufacture, re-label, warn or inform the unsuspecting consuming public. Defendant's reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys ' fees and all such other relief as the Court deems proper.

COUNT IV

FRAUDULENT MISREPRESENTATION AND/OR OMISSION

93. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

94. Defendant, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of the R3 ceramic liner, owed a duty to provide accurate and complete information regarding the R3 ceramic liner.

95. Prior to Plaintiff receiving the R3 ceramic liner in March 2010, Defendant fraudulently misrepresented that the R3 ceramic liner was a safe and effective device, and misrepresented material facts regarding the safety and efficacy of the R3 ceramic liner, including information regarding increased risk of fracture, harmful side-effects, and increased risk of revision surgery.

96. On or about March 2009, prior to Plaintiff receiving the R3 ceramic liner, and through at least June 30, 2009 and after, Defendant fraudulently misrepresented to the public in its R3 Design Rationale that the R3 ceramic liner was: "New technology; Improved manufacturing processes and standards; New designs. This translates into improvements in the following: Mechanical and physical properties; Wear characteristics; Optimized biocompatibility; Reliability expected by today's more active patients". The R3 Design Rationale also fraudulently stated: "Due to the reduced grain size, ceramic components are harder than before. That has led to wear rates as low as 0.00lmm/year." Further, the R3 Design Rationale stated: "Impingement in ceramic bearing systems increases wear and decreases implant longevity. The improved design of R3 ceramic acetabular components: Reduces the effects of impingement; Enhances wear and durability by utilizing liners that sit flush with the shell face". The R3 Design Rational also fraudulently stated: "The unique feature about R3 ceramic liners is that they come with a titanium support ring around the periphery of the liner. The support ring and ceramic liner are precisely assembled utilizing a cold pressing process, which assures that the material properties of the ceramic and titanium are not altered. Lab tests have shown that the burst strength of these liners is significantly higher than that of traditional ceramic liners with no band. Based on these test results, it can be hypothesized that these liners with titanium band would reduce the incidence of fracture of the ceramic liners."

97. Defendant made these representations to Plaintiff, Plaintiff’s physicians, and other consumers on the date of Plaintiff’s hip replacement surgery while knowing or having reason to know that these statements were false because the R3 ceramic liner was adulterated, was not manufactured in accordance with its PMA specifications, and could prematurely fracture.

98. Defendant had a duty to provide Plaintiff, Plaintiff’s physicians, and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the R3 ceramic liner they manufactured, marketed, distributed and sold.

99. Defendant, based on prior experience, adverse event reports, studies, and knowledge of the efficacy and safety failures associated with the R3 ceramic liner, including the FDA' s July

2010 inspection, knew or should have known that their representations regarding R3 ceramic liner were false, and had a duty to disclose the dangers associated with the device.

100. Defendant made representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance by purchasing the R3 ceramic liner.

101. On March 11, 2010, when Plaintiff was implanted with the defective R3 ceramic liner, Defendant failed to disclose to Plaintiff, Plaintiff's physicians, and the public that the R3 ceramic liner was adulterated, failed to conform to its PMA specifications, and could fracture. On or about July 2010 and prior to October 1, 2010, Defendant and John G.S. Buchanan, Chairman of Smith & Nephew, who approved and is one person responsible for the R3 Design Rationale, had a duty to correct false and misleading information in its R3 Design Rationale because on June 30, 2009, the R3 ceramic liner was adulterated, failed to conform to its PMA specifications, and could fracture, information which Defendant should have been publically disseminated prior to June 30, 2009, and Defendant should have corrected false information in its R3 Design Rationale prior to June 30, 2009. Through these fraudulent omissions and statements, Defendant has profited and benefited from payment Plaintiff made for the R3 ceramic liner and from payment Plaintiff has made for replacing the R3 ceramic liner.

102. Plaintiff and the medical community justifiably relied on Defendant representations and nondisclosures by purchasing and using the R3 ceramic liner.

103. Defendant's representations and nondisclosures regarding the safety and efficacy of the R3 ceramic liner were the direct and proximate cause of Plaintiff's injuries.

104. Defendant's fraudulent concealment tolled the statute of limitations because only Defendant knew the true dangers associated with the use of the R3 ceramic liner as described herein. Defendant did not disclose this info1mation to the Plaintiff, Plaintiff's physicians, the healthcare community and the general public. Without full knowledge of the dangers of the R3 ceramic liner, Plaintiff's claims could not be evaluated.

105. Plaintiff's R3 liner fractured prematurely, within three years from implant, due to Defendant's failure to comply with FDA PMA specifications resulting in the FDA's initial investigation in July 2010, the FDA's December 2010 Warning Letter and Defendant's ultimate recall.

106. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture and inadequate warnings of the R3 ceramic liner, Plaintiff's liner prematurely fractured, requiring revision surgery. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

107. Defendant's conduct, as described above, was fraudulent and reckless. Defendant risked the lives of consumers and users of their product, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendant made conscious decisions not to redesign, re-manufacture, re-label, warn or inform the unsuspecting public. Defendant's reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys ' fees and all such other relief as the Court deems proper.

COUNT V

BREACH OF EXPRESS WARRANTY

108. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

109. Defendant advertised, labeled, marketed and promoted the R3 ceramic liner, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a

way as to induce its purchase or use, thereby making an express warranty that the R3 ceramic liner would conform to the representations. More specifically, Defendant represented that the R3 ceramic liner was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

110. On or about March 2009, prior to Plaintiff receiving the R3 ceramic liner, and through at least June 30, 2009 and after, Defendant fraudulently misrepresented, which, upon information and belief, were made without FDA approval, to the public in its R3 Design Rationale that the R3 ceramic liner was: "New technology; Improved manufacturing processes and standards; New designs. This translates into improvements in the following: Mechanical and physical properties; Wear characteristics; Optimized biocompatibility; Reliability expected by today's more active patients". The R3 Design Rationale also fraudulently stated: "Due to the reduced grain size, ceramic components are harder than before. That has led to wear rates as low as 0.001 mm/year." Further, the R3 Design Rationale stated: "Impingement in ceramic bearing systems increases wear and decreases implant longevity. The improved design of R3 ceramic acetabular components: Reduces the effects of impingement; Enhances wear and durability by utilizing liners that sit flush with the shell face". The R3 Design Rational also fraudulently stated: "The unique feature about R3 ceramic liners is that they come with a titanium support ring around the periphery of the liner. The support ring and ceramic liner are precisely assembled utilizing a cold pressing process, which assures that the material properties of the ceramic and titanium are not altered. Lab tests have shown that the burst strength of these liners is significantly higher than that of traditional ceramic liners with no band. Based on these test results, it can be hypothesized that these liners with titanium band would reduce the incidence of fracture of the ceramic liners."

111. Defendant made these representations to Plaintiff, Plaintiff's physicians, and other consumers on the date of Plaintiff's hip replacement surgery while knowing or having reason to know that these statements were false because the R3 ceramic liner was adulterated, was not manufactured in accordance with its PMA specifications, and could fracture.

112. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

113. The R3 ceramic liner did not conform to the representations made by Defendant in that the R3 ceramic liner was not safe and effective for use by individuals such as Plaintiff, and the R3 ceramic liner was adulterated and failed to conform to its manufacturing specifications as confirmed by the FDA and Defendant's ultimate recall batches of the R3 ceramic liner, including the R3 ceramic liner implanted in Plaintiff.

114. At all relevant times, Plaintiff used the R3 ceramic liner for the purpose and in the manner intended by Defendant.

115. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized the danger inherent in the R3 ceramic liner.

116. The breach of warranty was a substantial factor in bringing about Plaintiff's injuries.

117. Plaintiff's R3 liner fractured prematurely, within three years from implant, due to Defendant's failure to comply with FDA PMA specifications resulting in the FDA's initial investigation in July 2010, the FDA's December 2010 Warning Letter and Defendant's ultimate recall.

118. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture and inadequate warnings of the R3 ceramic liner, Plaintiff's liner prematurely fractured, requiring revision surgery. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

119. As a direct and proximate result of Defendant's acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the R3 ceramic liner, Plaintiff was implanted with the R3 ceramic liner and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI

BREACH OF IMPLIED WARRANTY

120. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

121. The R3 ceramic liner was not reasonably fit for the ordinary purpose for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the R3 ceramic liner minimally safe for its expected purpose in that it was adulterated, was manufactured in violation of its PMA specifications, and could fracture prematurely.

122. At all relevant times, Plaintiff used the R3 ceramic liner for the purpose and in the manner intended by Defendant.

123. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

124. The breach of warranty was a substantial factor in bringing about Plaintiff's injuries.

125. Plaintiff's R3 liner fractured prematurely, within three years from implant, due to Defendant's failure to comply with FDA PMA specifications resulting in the FDA's initial investigation in July 2010, the FDA's December 2010 Warning Letter and Defendant's ultimate recall.

126. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture and inadequate warnings of the R3 ceramic liner, Plaintiff's liner prematurely fractured, requiring revision surgery. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

127. As a direct and proximate result of Defendant's acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the R3 ceramic liner, Plaintiff was implanted with the R3 ceramic liner and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys ' fees and all such other relief as the Court deems proper.

COUNT VII
VIOLATION OF CONSUMER PROTECTION STATUTE

128. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

129. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statute listed below when it failed to adequately warn consumers and the medical community of the safety risks associated with the R3 ceramic liner, including that the R3 ceramic liner was adulterated, was manufactured in violation of its PMA specifications, and could prematurely fracture. As a direct result of Defendant's deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, mental anguish and other compensable injuries.

130. Defendant engaged in unfair competition and/or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law§§ 349 *et seq.* and 350 *et seq.*

131. The actions and failure to act of Defendant, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of the R3 ceramic liner to fracture and fail prematurely and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or employment by Defendant of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendant in violation of the consumer protection statute listed above.

132. Plaintiff and Plaintiff’s medical providers relied upon Defendant's misrepresentations and omissions in selecting the R3 ceramic liner for Plaintiff’s use. At the time Plaintiff was implanted with the defective R3 ceramic liner, the Defendant was aware that the R3 ceramic liner failed to conform to manufacturing specifications resulting in an increased risk to premature fracture.

133. Plaintiff’s R3 liner fractured prematurely, within three years from implant, due to Defendant's failure to comply with FDA PMA specifications resulting in the FDA's initial investigation in July 2010, the FDA's December 2010 Warning Letter and Defendant's ultimate recall.

134. By reason of the unlawful acts engaged in by Defendant, Plaintiff has suffered ascertainable loss and damages.

135. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture and inadequate warnings of the R3 ceramic liner, Plaintiff's liner prematurely fractured, requiring revision surgery. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

136. As a direct and proximate result of Defendant's conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, mental anguish and other compensable injuries.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys ' fees and all such other relief as the Court deems proper.

COUNT XIII
UNJUST ENRICHMENT

137. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

138. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendant has profited and benefited from payment Plaintiff made for the R3 ceramic liner and from payment Plaintiff has made for replacing the R3 ceramic liner.

139. In exchange for the payment made for the R3 ceramic liner, and at the time payment was made, Plaintiff expected that the R3 ceramic liner was safe and medically effective treatment for the condition, illness, disorder, or symptom for which it was prescribed.

140. Defendant voluntarily accepted and retained Plaintiff's payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiff paid for the R3 ceramic liner and was forced to pay for a replacement device when Plaintiff otherwise would not have done so. The failure of Defendant to provide Plaintiff with the remuneration expected enriched Defendant unjustly.

141. Plaintiff is entitled in equity to seek restitution of Defendant's wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendant's unjust enrichment.

COUNT XIV
CONSUMER FRAUD

142. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

143. Defendants' wrongful conduct, individually and jointly constitute a violation of Section 349 of the New York Business Law Statute because they were deceptive acts or practices in the conduct of Defendants' business, trade or commerce in the furnishing of medical products to New York resident Plaintiffs.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial of this action;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Punitive damages;

4. Double or triple damages as allowed by law;

5. Restitution and disgorgement of profits;

6. Reasonable attorneys' fees;

7. The costs of these proceedings; and

8. Such other and further relief as this Court deems just and proper.

Dated: November 24, 2014

Respectfully submitted,

/s/ Terrence Smith

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CERTIFICATE OF SERVICE

I hereby certify that on November 24, 2014, I caused the foregoing to be filed through the Court's ECF System.

/s/ Terrence Smith

Terrence Smith